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DAVID W HIGHET VP AND CHIEF IP COUNSEL
BECTON DICKINSON AND COMPANY
1 BECTON DRIVE
MC110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
LU, FRANK WEI MIN	
ART UNIT	**PAPER NUMBER**
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,654	NADEAU ET AL.	
	Examiner	Art Unit	
	Frank W. Lu	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-114* is/are pending in the application.

4a) Of the above claim(s) *9,16-19,31-73 and 79-114* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-15,20-30 and 74-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/04 and 7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of species (b) (the hybridization blocker oligonucleotide comprises only a 5' sequence that is not complementary to the first oligonucleotide moiety in claim 3) in the reply filed on June 28, 2007 is acknowledged. The traversal is on the ground(s) that "[A]pplicants respectfully note that claims 2 and 3 (corresponding to species (a) and (b)) do not recite that the hybridization blocker oligonucleotide comprises 'only' a 3' or 5' sequence, respectively. Rather, claim 2 and 3 recite that the hybridization blocker oligonucleotid '*comprises*' a 3' or 5'sequence that is not complementary to the first oligonucleotide moiety. Accordingly, it is respectfully submitted that the hybridization blocker oligonucleotides operationally connect the methods of putative species (a), (b) and (c)".

After carefully considering applicant's arguments, the examiner agrees to withdraw the species election and combine species (a) to (c) for the examination. Therefore, claims 1-8, 10-15, 20-30, and 74-78 will be examined.

Drawings

2. Some words in Figure 13 are hard to read. New Figure 13 is required in response to this office action. No new matter may be introduced in the required drawing. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d).

Oath/Declaration

3. The examiner cannot locate a oath/declaration in this instant application.

Specification

4. The abstract of the disclosure is objected to because the length of the abstract is more than 150 words. Correction is required. See MPEP § 608.01(b).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-8, 10-15, and 20-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 is rejected as vague and indefinite in view of the phrase "the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties" in (d) of step (i) because a hybrid formed by the first portion of the first oligonucleotide moiety and the portion of the second oligonucleotide moiety must have 3' terminus of the first or second oligonucleotide moieties. Does this phrase mean that the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties that has an ability to extend in an amplification reaction or mean something else? Please clarify.

8. Claim 6 is rejected as vague and indefinite because it is unclear whether all of the bases of the first portion of the first oligonucleotide moiety are complementary to the hybridization

blocker oligonucleotide in a hybrid formed by the first oligonucleotide moiety and the hybridization blocker oligonucleotide or not. Please clarify.

9. Claim 15 is rejected as vague and indefinite because it is unclear what is combined with the hybridization blocker oligonucleotide. Please clarify.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-3, 6, 8, 13, 14, 21, 27, and 74-78 are rejected under 35 U.S.C. 102(e) as being anticipated by Kurn (US Patent No. 6,815,164, filed on October 9, 2001).

Regarding claim 1, Kurn teaches a method of detecting an analyte, comprising: (i) combining: (a) an analyte (ie., the target nucleic acid sequence); (b) a first proximity member, comprising a first analyte-specific binding entity that is capable of forming a complex with the analyte and that is conjugated to a first oligonucleotide moiety comprising a first portion (ie., the first probe); (c) a second proximity member, comprising a second analyte-specific binding entity that is capable of forming a complex with the analyte and that is conjugated to a second oligonucleotide moiety comprising a portion that is capable of hybridizing to the first portion of the first oligonucleotide (ie., the second probe); (d) a hybridization blocker oligonucleotide (ie., the third probe), where the hybridization blocker oligonucleotide comprises a portion that is

capable of forming a hybrid with the first portion of the first oligonucleotide moiety; (ii) forming a hybrid comprising the first portion of the first oligonucleotide moiety and the portion of the second oligonucleotide moiety, where the hybrid comprises a 3' terminus of the first or second oligonucleotide moieties; (iii) extending the 3' terminus to produce an amplicon; (iv) amplifying the amplicon to produce an amplification product; and (v) detecting the amplification product; wherein detection of the amplification product allows detection of the analyte (see claim 30 in columns 40 and 41, Examples 1 and 2 in columns 34-36, and Figure 13 with the examiner's handwritings).

Regarding claims 2, 6, and 8, Kurn teaches that the hybridization blocker oligonucleotide (ie., probe C in Figure 6) comprises a 3' sequence that is not complementary to the first oligonucleotide moiety as recited in claim 2 wherein the hybridization blocker oligonucleotide forms a hybrid comprising all of the bases of the first portion of the first oligonucleotide moiety as recited in claim 6 and the first portion of the first oligonucleotide moiety is about the length of the entire first oligonucleotide moiety as recited in claim 8 (see Figure 6).

Regarding claims 3, 13, and 14, Kurn teaches that the hybridization blocker oligonucleotide (ie., hairpin probe in Figure 12) comprises a 5' sequence that is not complementary to the first oligonucleotide moiety as recited in claim 3 wherein the hybridization blocker oligonucleotide comprises a double-stranded portion that is 3' of the portion of the hybridization blocker that is capable of forming a hybrid with the first portion of the first oligonucleotide moiety as recited in claim 13 and the double-stranded portion comprises a hairpin loop as recited in claim 14 (see Figure 12 and columns 23 and 24).

Regarding claims 21 and 27, Kurn teaches that said amplifying is by a method selected from the group consisting of polymerase chain reaction, strand displacement amplification, thermophilic strand displacement amplification, self-sustained sequence replication, nucleic acid sequence-based amplification, a Qβ replicase system, ligase chain reaction, and transcription mediated amplification as recited in claim 21 and the detecting is quantitative as recited in claim 27 (see Examples 1 and 2 in columns 34-36).

Regarding claims 74, 75, and 77, Kurn teaches a method of detecting an analyte, comprising: (i) combining: (a) an analyte (ie., the target nucleic acid); (b) a first proximity member, comprising a first analyte-specific binding entity that is capable of forming a complex with the analyte and that is conjugated to a first oligonucleotide moiety comprising a first portion (ie., the first probe); (c) a second proximity member, comprising a second analyte-specific binding entity that is capable of forming a complex with the analyte and that is conjugated to a second oligonucleotide moiety comprising a first portion (ie., the second probe); (ii) forming at least one hybrid comprising the first portion of the first oligonucleotide moiety and the first portion of the second oligonucleotide moiety, wherein the at least one hybrid comprises a 3' terminus that is capable of being extended to form a complement of a second portion of the first oligonucleotide moiety that comprises a 5' terminus; (iii) producing an amplicon; (iv) amplifying the amplicon to produce an amplification product; and (v) detecting the amplification product; wherein detection of the amplification product allows detection of the analyte as recited in claim 74 wherein the at least one hybrid comprises the first portions of the first and second oligonucleotides as recited in claim 75, and said producing an amplicon comprises extending the

3' terminus as recited in claim 77 (see claim 30 in columns 40 and 41, Examples 1 and 2 in columns 34-36, and Figure 13 with the examiner's handwritings).

Regarding claim 76, since the claim does not require that a splint oligonucleotide are different from an analyte recited in claim 1, here the examiner considers that a splint oligonucleotide is an analyte recited in claim 1. Thus, Kurn teaches two hybrids are formed, the first hybrid comprising the first portion of the first oligonucleotide moiety and a first portion of a splint oligonucleotide, and the second hybrid comprising the first portion of the second oligonucleotide moiety and a second portion of the splint oligonucleotide (see Figure 13 with the examiner's handwritings).

Regarding claim 78, since Kurn teaches to conjunct nucleic acid amplification techniques in Example 2 with ligation-based amplification (see column 28, lines 62-67 and column 29, lines 1-32 and Examples 1 and 2 in columns 35 and 36), Kurn discloses that said producing an amplicon comprises: (i) forming a hybrid between the second portion of the first oligonucleotide moiety and a third oligonucleotide and (ii) ligating the 3' terminus of the at least one hybrid to a 5' terminus of the third oligonucleotide.

Therefore, Kurn teaches all limitations recited in claims 1-3, 6, 8, 13, 14, 21, 27, and 74-78.

Conclusion

12. No claim is allowed.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of

such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

September 17, 2007

FRANK LU
PRIMARY EXAMINER